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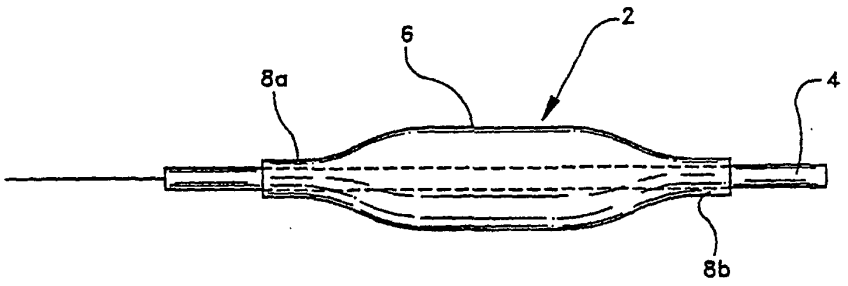

(57) Abstract

Disclosed is a dilatation balloon having a single layer containing polyesteretheramide copolymer. The dilatation balloon may also contain polyamide and/or additional polymers, and may contain substantially no polyetheramide having substantially no ester linkages.

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DILATATION BALLOONS CONTAINING POLYESTERETHERAMIDE COPOLYMER

Background of the Invention

The present invention is generally directed to dilatation balloons containing polyesteretheramide copolymer.

The use of balloon catheters for coronary angioplasty is known in the art. In an angioplasty procedure, a partially occluded blood vessel, i.e., one containing a stenosis, is treated by the use of an expanding balloon member which presses the stenosis back against the vessel wall. Typically, the expander member or balloon is carried on the distal end of a dilatation catheter which is routed through the vascular system to a location within, for example, a coronary artery containing a stenotic lesion. Following placement of the expander member across the lesion as desired, fluid is introduced into the proximal end of the catheter to inflate the expander member to a relatively high pressure, thereby restoring patency to the vessel. Coronary angioplasty procedures and angioplasty devices are described in detail in Vliestra et al., "Coronary Balloon Angioplasty," Blackwell Scientific Publications (1994).

Medical balloons that are known in the art are disclosed in the following documents: U.S. Patent Nos. 4 964 853 and 4 994 032 to Sugiyama et al; U.S. Patents No. 4 906 244, 5 108 415, 5 156 612, 5 236 659, and 5 304 197, to Pinchuk et al; U.S. Patent Nos. 5 226 880 and 5 334 148 to Martin; U.S. Patent No. 5 250 069 to

Nobuyoshi et al; U.S. Patent No. 5,328,468 to Kaneko et al.; European Patent Application No. 0 566 755; and Japanese laid-open patent application No. 58-188463. (All documents cited herein, including the foregoing, are incorporated herein in their entireties for all purposes.)

It is an object of the present invention to provide a balloon for an angioplasty device which is made, at least in part, of polyesteretheramide copolymer. Other objects and advantages of the invention will become apparent to those skilled in the art through familiarization with the specification and claims herein.

Summary of the Invention

In sum, the present invention relates to a balloon for an angioplasty device having a single polymeric layer. The layer may have from about 20 to about 100 weight percent polyesteretheramide copolymer and from about 0 to about 80 weight percent polyamide. The layer contains substantially no polyetheramide having substantially no ester linkages. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to about 75 Shore D, and more preferably from about 63 to about 72 Shore D. Even more preferably, the polyesteretheramide copolymer may have a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D. The single polymeric layer may contain at least about 2 weight percent polyamide such as nylon 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and

combinations thereof. The single polymeric layer may further contain at least about 2 weight percent polymer such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof. The polymeric layer may have at least about 40 weight percent polyesteretheramide copolymer and more preferably at least about 80 weight percent polyesteretheramide copolymer. The balloon may have from about 20 to about 80 weight percent nylon 12 and about 20 to about 80 weight percent polyesteretheramide copolymer, preferably about 60 weight percent nylon 12 and about 40 weight percent polyesteretheramide copolymer. Alternatively, the balloon may have about 25 to about 80 weight percent nylon 4/6 and about 20 to about 75 weight percent polyesteretheramide copolymer, preferably about 65 weight percent nylon 4/6 and about 35 weight percent polyesteretheramide copolymer.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer consisting essentially of a polyesteretheramide copolymer. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to about 75 Shore D, and more preferably about 63 to about 72 Shore D. Even more preferably the polyesteretheramide copolymer may have a hardness selected from 63 Shore D, 70 Shore D, and 72 Shore D. The balloon may consist of polyesteretheramide.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer having (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and (c) from 0 to 9 weight percent of a polymer other than polyesteretheramide and polyamide. The balloon may have at least about 95 weight percent polyesteretheramide copolymer.

Description of the Drawings

FIG. 1 is a perspective view of an expander member of the present invention joined to the distal end of a catheter;

FIG. 2 is a cross-sectional view of a balloon form used to make expander members of the present invention;

FIG. 3 is a schematic view of a mold apparatus used to make expander members of the present invention;

FIG. 4 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 6333 balloons;

FIG. 5 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 6333 balloons;

FIG. 6 shows a response surface that details the effects of processing variables and material selection on balloon K-stat for PEBAX 6333 balloons;

FIG. 7 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 6333 balloons;

FIG. 8 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 7033 balloons;

FIG. 9 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7033 balloons;

FIG. 10 shows a response surface that details the effects of processing variables and material selection on balloon K-stat 7033 for PEBAX 7033 balloons;

FIG. 11 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 7033 balloons;

FIG. 12 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 7233 balloons;

FIG. 13 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7233 balloons;

FIG. 14 shows a response surface that details the effects of processing variables and material selection on balloon K-stat for PEBAX 7233 balloons; and

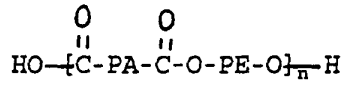
FIG. 15 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 7233 balloons.

Description of the Preferred Embodiments

With reference to FIG. 1, expander member 2 is attached to the distal end of a catheter shaft 4. The expander member 2, otherwise known as a balloon, has a single polymeric layer 6 which surrounds the catheter shaft 4. The expander member 2 shown is bonded at two

bonding sites 8a,b by thermal bonding, by laser bonding, with adhesives, or by other methods known in the art.

The expander members of the present invention contain polyesteretheramide copolymer. The structure of these polymers consists of regular and linear chains of rigid polyamide blocks and flexible polyether blocks. Such copolymers may be described by the following formula:



where PA is a polyamide block; and
where PE is a polyether block.

Polyesteretheramide copolymer materials are sold under the trademark PEBAX by Atochem Inc. of Glen Rock, New Jersey. Properties of several grades of PEBAX are disclosed in Atochem's brochure entitled "PEBAX Polyether Block Amide" (December 1987).

The expander member of the present invention may contain polyamide. Polyamide materials include nylon 12, nylon 11, nylon 6, nylon 6/6, and nylon 4/6. Such materials are sold under the trademark ZYTEL® by Dupont.

The expander member of the present invention may further contain a polymer other than polyesteretheramide copolymer or polyamide, such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

The single polymeric layer making up the expander member may be a blend of suitable materials. Such a blend may be created by mixing the desired resins and

then extruding these resins to form a parison. The single layer can also be a graft copolymer. Such a graft copolymer can be formed, for example, by reacting polyamide (such as Nylon 12) with polyphenylether graft maleic anhydride (PPE-graft-MA). So called polymer alloys, and the like, are also included within the purview of this application.

The expander member of the present invention may be formed by first generating a parison in an extruder. The parison will typically have an inside diameter of from about .01 to .031 inches (0.025 to 0.079 cm), and a wall thickness of from about .0035 to .015 inches (.0089 to 0.038 cm).

Hot water treated molding devices may then be utilized to blow mold the expander members of the present invention. Tubing of the desired material and having a required size and thickness is inserted into a balloon processing mold and heated to a temperature of from about 200-212°F (93-100°C). Weight may be added to the mold as desired. The tubing is subjected to longitudinal tension and high-pressure nitrogen 380-500 psi is introduced into the tubing in the mold. The mold remains in a hot water bath for a predetermined period of time of from about 10-45 seconds, preferably 25 seconds. The mold is then removed and placed in a cooling pot for a predetermined period of time of from about 20-40 seconds, preferably 30 seconds, after which the mold may be opened and the balloon removed.

In an alternative process, the balloons are formed in balloon blow molding machines. The tubing is inserted

into the mold and the ends of the tubing secured into mold gaskets. The tubing is thereafter heated in the range of 190-220°F (87-104°C) for about 10 to 45 seconds, preferably 25-30 seconds, and the heated tubing is subjected to longitudinal tension and expanded 1-2 times its length in the axial direction. The stretched tubing is pressurized with nitrogen in the range of about 350-500 psi and heat treated in the mold for about 10-20 seconds at about 250-280°F (121-138°C), preferably about 260-270°F (127-132°C). The mold is then cooled to room temperature and allowed to set at room temperature in the mold under pressure for approximately 10 to 15 seconds. Thereafter, the system can be depressurized and the balloon removed from the mold.

Examples

Balloons were made of polyesteretheramide block copolymer and then tested to determine certain characteristics.

Examples 1-180

180 balloons were made according to the following process:

Parisons of 100 weight percent polyesteretheramide block copolymer were extruded. The parisons had inside diameters of about .015 inches to about .023 inches, wall thicknesses of about .006 inches to about .010 inches, and lengths of about 18 inches.

The parisons were placed in the mold apparatus illustrated in FIGS. 2 and 3. As shown in FIG. 2, the balloon form 8 had a void 10 corresponding to the final shape of the expander member. The void was made up by a

proximal form 24, a body form 26, and a distal form 28. With reference to FIG. 3, the distal end of the parison was inserted into the proximal end 14 of the mold apparatus 12, and pushed through the proximal form 24, the body form 26, and the distal form 28 until it exited the distal end 16 of the mold section. Cap 18 was then placed over the distal end 16 of the apparatus 12 thereby clamping and sealing the distal end of the parison. The mold was then placed in a handle 20 such that the proximal end of the parison freely extended from the handle 20. Weights 22 were then placed over the proximal end of the parison and onto the mold.

The open proximal end of the parison was then connected to a pressurized nitrogen source by a Touhy Borst clamp. The nitrogen source was capable of achieving maximum pressures of 1,000 psi. The nitrogen source was then opened to varying degrees of between 350-500 psi and the mold was placed in a bath of hot water (212°F). The hot water bath warmed the parison. The freely extending proximal end of the parison was held by hand such that only about the distal form 28 was under water, until the mold dropped due to longitudinal stretching and the distal end of the parison expanded radially (about 15-30 seconds). Still holding the mold by hand, the mold continued to drop until it was entirely under water and the proximal end of the balloon expanded radially (about an additional 1-10 seconds).

The mold was then removed from the hot water bath and placed in a cold water bath of about 60-75°F for

about 30 seconds. The nitrogen was then shut off, and the balloon was removed from the mold.

The balloons were tested by attaching the balloons to a pressurized nitrogen source in a 37°C water bath, expanding the balloons under several predetermined pressures of nitrogen (50 psi, 100 psi, 150 psi, and burst pressure), and then measuring several dimensions and the burst pressure of the balloons. Dimensions were measured with a snap gauge.

Tables 1-18 below list certain parameters of the process utilized to make the subject balloons (hot pot temperature, cold pot temperature, weight added to mold, and nitrogen pressure). The tables also show results of the testing of the expander members. K stat was calculated as follows: (Burst pressure)-((K Stat)(Burst Pressure Standard Deviation)). Hoop stress was calculated as follows: (Balloon Burst Pressure) (Balloon Diameter)/(2)(Balloon Wall Thickness).

Table 1

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
1	0.001250	0.001300	0.001250	.017x.031	0.1120	0.1200	0.1260	255
2	0.001350	0.001300	0.001300	.017x.031	0.1120	0.1200	0.1250	266
3	0.001400	0.001300	0.001300	.017x.031	0.1125	0.1210	0.1250	269
4	0.001300	0.001400	0.001250	.017x.031	0.1120	0.1200	0.1250	270
5	0.001350	0.001400	0.001300	.017x.031	0.1130	0.1200	0.1260	270
6	0.001350	0.001400	0.001300	.017x.031				252
7	0.001350	0.001400	0.001300	.017x.031				268
8	0.001300	0.001400	0.001300	.017x.031				270
9	0.001300	0.001350	0.001300	.017x.031				268
10	0.001350	0.001450	0.001300	.017x.031				280
Average	0.001330	0.001370	0.001290	.017x.031	0.11230	0.12020	0.12540	266.8
Standard	4.2164E-05	5.37484E-05	2.10819E-05		0.000447	0.000447	0.000548	7.9693859

Calculated K-stat (psi): 225.3353
Calculated Hoop Stress (psi): 24112

Table 2

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 300 GRAMS
NITROGEN 480 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
11	0.00190	0.00190	0.00190	.015X.035	0.1080	0.1180	0.1230	300
12	0.00180	0.00185	0.00180	.015X.035	0.1090	0.1180	0.1220	275
13	0.00170	0.00185	0.00165	.015X.035	0.1090	0.1180	0.1220	296
14	0.00180	0.00180	0.00180	.015X.035	0.1075	0.1170	0.1220	285
15	0.00190	0.00195	0.00170	.015X.035	0.1080	0.1180	0.1220	285
16	0.00180	0.00185	0.00160	.015X.035				300
17	0.00180	0.00180	0.00180	.015X.035				293
18	0.00190	0.00185	0.00170	.015X.035				315
19	0.00185	0.00180	0.00165	.015X.035				285
20	0.00170	0.00170	0.00170	.015X.035				285
Average	0.001815	0.001835	0.00173	.015X.035	0.1083	0.1178	0.1222	291.9
Standard	7.47E-05	6.687E-05	9.18937E-05		0.000671	0.000447	0.000447	11.34754

Calculated K-stat (psi): 232.8587
Calculated Hoop Stress (psi): 28594

Table 3

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 440 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
21	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	293
22	0.00160	0.00160	0.00160	.017X.034	0.111	0.120	0.126	270
23	0.00170	0.00170	0.00170	.017X.034	0.111	0.120	0.125	293
24	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	291
25	0.00160	0.00160	0.00160	.017X.034	0.110	0.121	0.125	293
26	0.00155	0.00150	0.00150	.017X.034				283
27	0.00170	0.00170	0.00170	.017X.034				293
28	0.00160	0.00160	0.00160	.017X.034				293
29	0.00170	0.00170	0.00170	.017X.034				287
30	0.00170	0.00170	0.00170	.017X.034				293
Average	0.001655	0.001650	0.001650	.017X.034	0.11040	0.12060	0.12520	288.9
Standard	5.99E-05	7.071E-05	7.07107E-05		0.000548	0.000548	0.000447	7.460265

Calculated K-stat (psi): 250.0842
Calculated Hoop Stress (psi): 21052

Table 4

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 300 GRAMS
NITROGEN 320 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
31	0.00140	0.00140	0.00140	.020X.032	0.117	0.123	0.128	251
32	0.00140	0.00140	0.00140	.020X.032	0.117	0.123	0.129	249
33	0.00125	0.00125	0.00120	.020X.032	0.117	0.123	0.129	253
34	0.00135	0.00130	0.00120	.020X.032	0.116	0.123	0.129	251
35	0.00140	0.00130	0.00130	.020X.032	0.116	0.123	0.128	253
36	0.00140	0.00140	0.00135	.020X.032				243
37	0.00140	0.00135	0.00135	.020X.032				223
38	0.00130	0.00130	0.00130	.020X.032				253
39	0.00135	0.00135	0.00135	.020X.032				223
40	0.00135	0.00135	0.00125	.020X.032				253
Average	0.001360	0.00134	0.0013100	.020X.032	0.1166	0.123	0.1286	245.2
Standard	5.16E-05	5.164E-05	7.37865E-05		0.000548	1.86E-09	0.000548	12.0904

Calculated K-stat (psi): 182.2936
Calculated Hoop Stress (psi): 22176

Table 5

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
41	0.00160	0.00160	0.00160	.020X.035	0.115	0.125	0.130	253
42	0.00170	0.00170	0.00170	.020X.035	0.117	0.125	0.130	263
43	0.00160	0.00170	0.00170	.020X.035	0.117	0.125	0.130	269
44	0.00140	0.00150	0.00150	.020X.035	0.118	0.126	0.131	253
45	0.00145	0.00155	0.00150	.020X.035	0.114	0.123	0.129	250
46	0.00160	0.00160	0.00160	.020X.035				269
47	0.00150	0.00150	0.00140	.020X.035				268
48	0.00140	0.00140	0.00140	.020X.035				239
49	0.00150	0.00150	0.00150	.020X.035				257
50	0.00150	0.00150	0.00150	.020X.035				257
Average	0.001525	0.001555	0.001540	.020X.035	0.1162	0.1248	0.13	257.8
Standard	9.79E-05	9.56E-05	0.000107497		0.001643	0.001095	0.000707	9.681598

Calculated K-stat (psi): 207.4266
Calculated Hoop Stress (psi): 21097

Table 6

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 200° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
51	0.00165	0.00165	0.0016	.023X.035	0.118	0.127	0.136	223
52	0.00130	0.00130	0.0013	.023X.035	0.118	0.130	0.138	223
53	0.00130	0.00140	0.0013	.023X.035	0.117	0.127	0.135	239
54	0.00140	0.00140	0.0014	.023X.035	0.118	0.128	0.136	239
55	0.00150	0.00160	0.0016	.023X.035	0.118	0.127	0.136	239
56	0.00150	0.00150	0.0015	.023X.035				250
57	0.00140	0.00140	0.0014	.023X.035				250
58	0.00130	0.00130	0.0013	.023X.035				238
59	0.00130	0.00130	0.0013	.023X.035				253
60	0.00130	0.00130	0.0013	.023X.035				239
Average	0.001395	0.001415	0.0014	.023X.035	0.1178	0.1278	0.1362	239.3
Standard	0.000121	0.0001292	0.000124722		0.000447	0.001304	0.001095	10.27456

Calculated K-stat (psi): 185.8414
Calculated Hoop Stress (psi): 21922

Table 7

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
61	0.00150	0.00150	0.0015	.023X.038	0.118	0.126	0.134	253
62	0.00150	0.00150	0.0015	.023X.038	0.119	0.126	0.135	253
63	0.00160	0.00160	0.0016	.023X.038	0.121	0.130	0.138	260
64	0.00160	0.00160	0.0016	.023X.038	0.120	0.127	0.138	245
65	0.00140	0.00140	0.0014	.023X.038	0.120	0.127	0.139	253
66	0.00160	0.00160	0.0015	.023X.038				253
67	0.00160	0.00160	0.0016	.023X.038				253
68	0.00160	0.00160	0.0016	.023X.038				263
69	0.00170	0.00170	0.0017	.023X.038				253
70	0.00145	0.00145	0.0015	.023X.038				258
Average	0.001555	0.001555	0.00155	.023X.038	0.1196	0.1272	0.1368	254.4
Standard	8.96E-05	8.96E-05	8.49837E-05		0.00114	0.001643	0.002168	4.926121

Calculated K-stat (psi): 228.7694
Calculated Hoop Stress (psi): 20810

Table 8

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 460 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
71	0.00145	0.00155	0.00155	.017X.034	0.1110	0.119	0.123	305
72	0.00150	0.00150	0.00150	.017X.034	0.1100	0.120	0.124	307
73	0.00145	0.00150	0.00155	.017X.034	0.1100	0.118	0.123	293
74	0.00140	0.00150	0.00150	.017X.034	0.1100	0.120	0.123	323
75	0.00145	0.00155	0.00150	.017X.034	0.1100	0.118	0.124	309
76	0.00160	0.00150	0.00150	.017X.034				295
77	0.00150	0.00140	0.00145	.017X.034				323
78	0.00140	0.00140	0.00140	.017X.034				293
79	0.00150	0.00150	0.00150	.017X.034				320
80	0.00150	0.00150	0.00150	.017X.034				303
Average	0.001475	0.00149	0.001495	.017X.034	0.1102	0.119	0.1234	307.1
Standard	5.89E-05	5.164E-05	4.37798E-05		0.000447	0.001	0.000548	11.74214

Calculated K-stat (psi): 246.0057
Calculated Hoop Stress (psi): 24776

Table 9

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 205° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 380 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
81	0.00115	0.00115	0.00115	.020X.032	0.114	0.120	0.125	270
82	0.00125	0.00125	0.00115	.020X.032	0.113	0.120	0.125	270
83	0.00130	0.00130	0.00120	.020X.032	0.114	0.120	0.125	270
84	0.00120	0.00120	0.00110	.020X.032	0.113	0.120	0.125	270
85	0.00120	0.00120	0.00115	.020X.032	0.115	0.121	0.126	270
86	0.00115	0.00115	0.00110	.020X.032				250
87	0.00115	0.00120	0.00110	.020X.032				271
88	0.00115	0.00120	0.00115	.020X.032				270
89	0.00125	0.00120	0.00120	.020X.032				270
90	0.00120	0.00115	0.00115	.020X.032				269
Average	0.0012	0.0012	0.001145	.020X.032	0.1138	0.1202	0.1252	268
Standard	5.27E-05	4.714E-05	3.68932E-05		0.000837	0.000447	0.000447	6.342099

Calculated K-stat (psi): 235.0021
Calculated Hoop Stress (psi): 26844

Table 10

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 250 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
91	0.00130	0.00135	0.00140	.020X.035	0.109	0.119	0.125	295
92	0.00130	0.00135	0.00140	.020X.035	0.115	0.124	0.128	300
93	0.00130	0.00135	0.00130	.020X.035	0.115	0.122	0.127	289
94	0.00130	0.00135	0.00130	.020X.035	0.113	0.124	0.130	298
95	0.00130	0.00140	0.00130	.020X.035	0.115	0.124	0.128	283
96	0.00135	0.00135	0.00135	.020X.035				297
97	0.00140	0.00140	0.00140	.020X.035				297
98	0.00140	0.00140	0.00140	.020X.035				297
99	0.00140	0.00130	0.00140	.020X.035				290
100	0.00130	0.00130	0.00130	.020X.035				290
Average	0.001335	0.001355	0.001355	.020X.035	0.1134	0.1226	0.1276	293.6
Standard	4.74E-05	3.689E-05	4.97214E-05		0.002608	0.002191	0.001817	5.337498

Calculated K-stat (psi): 265.829
Calculated Hoop Stress (psi): 26962

Table 11

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
101	0.0014	0.0014	0.00140	.023X.035	0.115	0.121	0.127	298
102	0.0013	0.0013	0.00125	.023X.035	0.117	0.126	0.134	253
103	0.0013	0.0013	0.00120	.023X.035	0.117	0.126	0.131	275
104	0.0013	0.0013	0.00130	.023X.035	0.118	0.126	0.132	238
105	0.0013	0.0013	0.00140	.023X.035	0.116	0.127	0.133	281
106	0.0013	0.0013	0.00140	.023X.035				280
107	0.0013	0.0013	0.00140	.023X.035				269
108	0.0012	0.0012	0.00130	.023X.035				280
109	0.0012	0.0012	0.00125	.023X.035				283
110	0.0012	0.0012	0.00125	.023X.035				283
Average	0.00128	0.00128	0.001315	.023X.035	0.1166	0.1252	0.1314	274
Standard	6.32E-05	6.325E-05	7.83511E-05		0.00114	0.002387	0.002702	17.06849

Calculated K-stat (psi): 185.1926
Calculated Hoop Stress (psi): 26800

Table 12

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
111	0.00150	0.0015	0.0014	.023X.038	0.119	0.125	0.130	310
112	0.00160	0.0016	0.0016	.023X.038	0.118	0.125	0.130	300
113	0.00160	0.0016	0.0016	.023X.038	0.118	0.125	0.130	293
114	0.00150	0.0015	0.0015	.023X.038	0.118	0.126	0.131	283
115	0.00150	0.0015	0.0015	.023X.038	0.119	0.125	0.130	280
116	0.00150	0.0016	0.0015	.023X.038				300
117	0.00145	0.0015	0.0015	.023X.038				310
118	0.00160	0.0016	0.0016	.023X.038				298
119	0.00150	0.0015	0.0015	.023X.038				298
120	0.00145	0.0015	0.0015	.023X.038				313
Average	0.00152	0.00154	0.00152	.023X.038	0.1184	0.1252	0.1302	298.5
Standard	5.87E-05	5.164E-05	6.32456E-05		0.000548	0.000447	0.000447	11.01766

Calculated K-stat (psi): 241.1751
Calculated Hoop Stress (psi): 24586

Table 13

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 300 GRAMS
NITROGEN 460 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
121	0.00110	0.00120	0.00110	.017x.031	0.108	0.116	0.120	330
122	0.00120	0.00135	0.00120	017x031	0.106	0.115	0.119	345
123	0.00130	0.00140	0.00135	017x031	0.106	0.116	0.120	300
124	0.00130	0.00130	0.00120	017x031	0.106	0.116	0.120	345
125	0.00130	0.00130	0.00125	017x031	0.108	0.116	0.120	360
126	0.00135	0.00130	0.00120	017x031				345
127	0.00145	0.00130	0.00130	017x031				375
128	0.00130	0.00130	0.00130	017x031				330
129	0.00145	0.00130	0.00140	017x031				300
130	0.00140	0.00140	0.00135	017x031				345
Average	0.001315	0.001315	0.001265	.017x.031	0.10680	0.11580	0.11980	337.5
Standard	0.000108	5.798E-05	9.14391E-05		0.001095	0.000447	0.000447	23.71708

Calculated K-stat (psi): 214.1
Calculated Hoop Stress (psi): 29720

Table 14

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 500 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
131	0.00150	0.00150	0.0015	.017X.034	0.11	0.116	0.121	303
132	0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	280
133	0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	353
134	0.00155	0.00155	0.0015	.017X.034	0.11	0.117	0.120	340
135	0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	348
136	0.00160	0.00160	0.0016	.017X.034				338
137	0.00160	0.00160	0.0016	.017X.034				350
138	0.00170	0.00170	0.0017	.017X.034				369
139	0.00170	0.00170	0.0017	.017X.034				318
140	0.00170	0.00170	0.0017	.017X.034				353
Average	0.001615	0.001615	0.00161	.017X.034	0.11	0.1162	0.1208	335.2
Standard	6.69E-05	6.687E-05	7.37865E-05		0.0	0.000447	0.000447	27.01769

Calculated K-stat (psi): 194.627
Calculated Hoop Stress (psi): 24117

Table 15

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
141	0.00140	0.00140	0.00140	.020X.035	0.112	0.120	0.125	359
142	0.00140	0.00150	0.00150	.020X.035	0.112	0.118	0.125	325
143	0.00140	0.00150	0.00150	.020X.035	0.113	0.118	0.123	329
144	0.00150	0.00150	0.00150	.020X.035	0.111	0.120	0.123	359
145	0.00150	0.00150	0.00150	.020X.035	0.113	0.120	0.124	350
146	0.00145	0.00150	0.00150	.020X.035				330
147	0.00150	0.00160	0.00160	.020X.035				343
148	0.00140	0.00130	0.00130	.020X.035				353
148	0.00155	0.00155	0.00155	.020X.035				309
150	0.00150	0.00150	0.00150	.020X.035				343
Average	0.00146	0.001485	0.001485	.020X.035	0.1122	0.1192	0.124	340
Standard	5.68E-05	8.182E-05	8.18196E-05		0.000837	0.001095	0.001	16.38427

Calculated K-stat (psi): 254.7526
Calculated Hoop Stress (psi): 27018

Table 16

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 205° F.
COLD POT: ROOM TEMP.
WEIGHT: 320 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
151	0.0013	0.00125	0.001250	.020X.032	0.114	0.119	0.123	357
152	0.0013	0.00135	0.001300	.020X.032	0.113	0.119	0.123	359
153	0.0013	0.00120	0.001200	.020X.032	0.113	0.119	0.123	359
154	0.0012	0.00125	0.001200	.020X.032	0.112	0.119	0.123	369
155	0.0013	0.00120	0.001200	.020X.032	0.113	0.118	0.123	353
156	0.0012	0.00125	0.001250	.020X.032				343
157	0.0014	0.00135	0.001350	.020X.032				359
158	0.0013	0.00130	0.001300	.020X.032				359
159	0.0012	0.00120	0.001150	.020X.032				361
160	0.0013	0.00130	0.001250	.020X.032				313
Average	0.00126	0.001265	0.001245	.020X.032	0.113	0.1188	0.12300	353.2
Standard	4.9721E-05	5.798E-05	5.98609E-05		0.000707	0.000447	1.86E-09	15.56206

Calculated K-stat (psi): 272.2306
Calculated Hoop Stress (psi): 33342

Table 17

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
COLD POT: ROOM TEMP.
WEIGHT: 380 GRAMS
NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
161	0.00140	0.00140	0.00140	.023X.035	0.116	0.122	0.126	329
162	0.00150	0.00150	0.00140	.023X.035	0.116	0.122	0.127	329
163	0.00140	0.00140	0.00150	.023X.035	0.116	0.123	0.128	330
164	0.00140	0.00140	0.00150	.023X.035	0.116	0.123	0.128	270
165	0.00135	0.00135	0.00135	.023X.035	0.117	0.124	0.129	343
166	0.00140	0.00140	0.00140	.023X.035				300
167	0.00140	0.00140	0.00150	.023X.035				345
168	0.00140	0.00140	0.00140	.023X.035				329
169	0.00140	0.00140	0.00140	.023X.035				330
170	0.00140	0.00140	0.00140	.023X.035				330
Average	0.001405	0.001405	0.001425	.023X.035	0.1162	0.1228	0.1276	323.5
Standard	3.69E-05	3.689E-05	5.40062E-05		0.000447	0.000837	0.00114	22.29723

Calculated K-stat (psi): 207.4875
Calculated Hoop Stress (psi): 28274

Table 18

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT:
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
171	0.00160	0.00160	0.001550	.023X.038	0.114	0.120	0.126	375
172	0.00160	0.00160	0.001600	.023X.038	0.115	0.122	0.126	300
173	0.00165	0.00160	0.001500	.023X.038	0.119	0.125	0.128	298
174	0.00160	0.00165	0.001600	.023X.038	0.116	0.122	0.127	328
175	0.00160	0.00160	0.001600	.023X.038	0.116	0.123	0.126	343
176	0.00170	0.00170	0.001700	.023X.038				370
177	0.00160	0.00170	0.001600	.023X.038				370
178	0.00170	0.00170	0.001700	.023X.038				355
179	0.00165	0.00170	0.001650	.023X.038				358
180	0.00170	0.00170	0.001700	.023X.038				373
Average	0.00164	0.001655	0.00162	.023X.038	0.116	0.1224	0.1266	347
Standard	4.59E-05	4.972E-05	6.74949E-05		0.001871	0.001817	0.000894	29.23088

Calculated K-stat (psi): 194.9117
Calculated Hoop Stress (psi): 25898

Examples 181-206

26 balloons were made according to the process described for Examples 1-180, except that the mold apparatus did not utilize weights 22 separately, but rather incorporated a preselected weight into handle 20.

The balloons were tested to measure distension and balloon burst strength. Distension is defined as the ratio of two balloon diameters. In this test, a balloon was inflated to a series of pressures. The diameter was measured at each pressure. The distension is the ratio of the diameter at the lowest pressure to the diameter at the highest pressure. Inflation was performed at 1 bar increments up to burst pressure.

To test the balloons, the balloons were first placed in temperature controlled water bath, and warmed for a minimum of 1 minute in water. The balloons were then attached to a pneumatic inflation/deflation device. A vacuum was created. Starting with a 4 bar pressure for 20 seconds, the balloon diameter and length were measured. The balloons were deflated, and the measurements were recorded. Increasing the pressure by 1 bar, the balloon diameters and lengths were measured. This procedure was repeated until the balloons bursted. The burst pressure and the type of burst profile were recorded.

Tables 19-21 below show the results of the testing of the expander members.

Table 19

PEBAX GRADE 7233

Tubing Dimensions (ID x OD): 0.48 x 0.81 mm
Balloon Dimensions (OD x length): 3.0 x 20 mm
Diameter Form: 3.00 mm

	DIAMETER (mm)										
	Balloon Number										
atm	181	182	183	184	185	186	187	188	189	190	Average
4	2.57	2.60	3	2.60	2.57	2.55	2.54	2.54	2.61	2.57	2.58
6	2.79	2.81	3	2.81	2.79	2.79	2.70	2.75	2.78	2.80	2.78
8	2.91	2.94	3	2.93	2.93	2.95	2.89	2.88	2.93	2.93	2.92
10	3.01	3.01	3	3.02	3.02	3.01	2.99	3.00	3.00	3.02	3.01
12	3.06	3.07	3	3.08	3.09	3.08	3.03	3.05	3.06	3.07	3.07
14	3.12	3.14	3	3.13	3.12	3.12	3.09	3.11	3.12	3.12	3.12
16	3.17	3.17	3	3.17	3.18	3.17	3.14	3.16	3.16	3.18	3.17
18	3.23	3.24	3	3.25	3.24	3.23	3.21	3.22	3.23	3.23	3.23

Average burst pressure	21.1 atm
Minimum burst pressure	20.0 atm
Maximum burst pressure	22.0 atm

Table 20

PEBAX GRADE 7233

Tubing Dimensions (ID x OD): 0.48 x 0.82 mm
Balloon Dimensions (OD x length): 3.0 x 20 mm
Diameter Form: 3.25 mm

	DIAMETER (mm)										
	Balloon Number										
atm	191	192	193	194	195	196	197	198			Average
4	2.73	2.74	2.66	2.71	2.69	2.71	2.70	2.77			2.71
6	2.97	2.93	2.89	2.92	2.92	2.94	2.97	3.01			2.94
8	3.12	3.06	3.03	3.08	3.06	3.07	3.08	3.12			3.08
10	3.18	3.12	3.15	3.16	3.12	3.17	3.18	3.19			3.16
12	3.23	3.20	3.22	3.23	3.19	3.23	3.23	3.26			3.22
14	3.30	3.27	3.27	3.27	3.25	3.28	3.28	3.33			3.28
16	3.33	3.31	3.31	3.30	3.29	3.32	3.32	3.36			3.32
18	3.39	3.33	3.37	3.37	3.36	3.40	3.39	3.43			3.38

Average burst pressure	21.4 atm
Minimum burst pressure	20.0 atm
Maximum burse pressure	22.0 atm

Table 21

PEBAX GRADE 7233

Tubing Dimensions (ID x OD): 0.65 x 0.90 mm
Balloon Dimensions (OD x length): 3.0 x 20 mm
Diameter Form: 3.25 mm

	DIAMETER (mm)										
	Balloon Number										
atm	199	200	201	202	203	204	205	206			Average
4	2.91	2.92	2.94	2.91	2.87	2.85	2.93	2.99			2.92
6	3.17	3.15	3.16	3.13	3.14	3.10	3.17	3.19			3.15
8	3.28	3.32	3.29	3.29	3.28	3.25	3.31	3.33			3.29
10	3.40	3.44	3.41	3.39	3.40	3.36	3.42	3.44			3.41
12	3.52	3.52	3.49	3.52	3.51	3.48	3.52	3.53			3.51
14	3.66	3.65	3.64	3.65	3.65	3.62	3.66	3.66			3.65
16	3.79	3.79	3.82	3.83	3.80	3.78	3.82	3.85			3.81
18	4.05	-	-	-	4.06	4.08	4.05	4.17			4.08

Average burst pressure	19.3 atm
Minimum burst pressure	18.0 atm
Maximum burse pressure	20.0 atm

Examples 207-236

30 balloons were made according to the procedure described above for Examples 1-180, except that parisons had inside diameters of about .025 inches and wall thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

Tables 22-28 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 22

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	207	208	209	210	211
4	58.8	.111	.111	.112	.112	.112
5	73.5	.113	.114	.115	.114	.115
6	88.2	.116	.116	.117	.116	.117
7	102.5	.118	.117	.118	.117	.118
8	117.6	.119	.119	.119	.118	.119
9	132.3	.120	.120	.120	.119	.120
10	147.0	.122	.121	.121	.120	.121
11	161.7	.122	.122	.122	.121	.122
12	176.4	.123	.123	.123	.122	.123
13	191.1	.124	.124	.124	.123	.124
14	205.8	.125	.125	.125	.124	.125
15	220.5	.126	.126	.125	.125	.126
16	235.2	.127	.127	.126	.125	.127
Burst Pressure (psi)		278	249	278	307	291
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 23

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	212	213	214	215	216
4	58.8	.113	.113	.111	.112	.111
5	73.5	.115	.115	.114	.114	.114
6	88.2	.117	.117	.116	.116	.116
7	102.5	.118	.118	.118	.118	.117
8	117.6	.119	.119	.119	.119	.118
9	132.3	.120	.120	.120	.120	.120
10	147.0	.121	.121	.121	.121	.120
11	161.7	.122	.122	.122	.122	.121
12	176.4	.123	.123	.123	.123	.122
13	191.1	.124	.124	.124	.124	.123
14	205.8	.125	.125	.125	.125	.124
15	220.5	.126	.126	.126	.126	.125
16	235.2	.127	.127	.127	.127	.126
Burst Pressure (psi)		266	264	280	290	280
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 24

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	217	218	219	220	221
4	58.8	.109	.110	.110	.109	.109
5	73.5	.112	.114	.114	.112	.114
6	88.2	.114	.116	.115	.114	.116
7	102.5	.116	.117	.117	.116	.118
8	117.6	.117	.119	.118	.117	.119
9	132.3	.119	.119	.120	.119	.120
10	147.0	.120	.120	.121	.120	.121
11	161.7	.121	.121	.122	.121	.122
12	176.4	.122	.122	.123	.122	.123
13	191.1	.123	.124	.124	.123	.124
14	205.8	.124	.125	.125	.124	.125
15	220.5	.125	.126	.126	.125	.126
16	235.2	.125	.127	.127	.126	.127
Burst Pressure (psi)		290	250	250	250	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 25

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	222	223	224	225	226
4	58.8	.108	.111	.111	.111	.110
5	73.5	.110	.114	.114	.113	.113
6	88.2	.112	.116	.116	.115	.115
7	102.5	.114	.118	.117	.117	.117
8	117.6	.116	.119	.118	.118	.118
9	132.3	.117	.120	.120	.119	.119
10	147.0	.119	.121	.121	.120	.120
11	161.7	.120	.122	.122	.121	.121
12	176.4	.121	.123	.123	.122	.122
13	191.1	.122	.124	.124	.123	.123
14	205.8	.123	.125	.125	.124	.124
15	220.5	.124	.126	.126	.125	.125
16	235.2	.125	.127	.127	.126	.126
Burst Pressure (psi)		264	280	260	280	290
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 26

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	227	228	229	230	231
4	58.8	.111	.111	.110	.111	.110
5	73.5	.113	.114	.113	.113	.113
6	88.2	.115	.116	.114	.115	.115
7	102.5	.117	.118	.116	.117	.117
8	117.6	.119	.119	.118	.118	.118
9	132.3	.120	.120	.119	.119	.119
10	147.0	.121	.121	.120	.120	.120
11	161.7	.122	.122	.121	.121	.121
12	176.4	.123	.123	.123	.122	.122
13	191.1	.123	.124	.124	.123	.123
14	205.8	.124	.125	.125	.124	.124
15	220.5	.125	.126	.126	.125	.125
16	235.2	.126	.127	.127	.126	.126
Burst Pressure (psi)		278	280	265	260	260
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 27

BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	232	233	234	235	236
4	58.8	.111	.111	.110	.111	.112
5	73.5	.114	.114	.113	.114	.115
6	88.2	.116	.116	.116	.116	.1165
7	102.5	.117	.117	.117	.117	.118
8	117.6	.119	.190	.118	.1185	.119
9	132.3	.120	.120	.119	.120	.120
10	147.0	.121	.121	.1205	.121	.121
11	161.7	.122	.122	.122	.122	.122
12	176.4	.1225	.123	.123	.123	.123
13	191.1	.124	.124	.124	.124	.124
14	205.8	.124	.125	.125	.125	.125
15	220.5	.125	.126	.125	.126	.126
16	235.2	.126	.127	.126	.127	.127
Burst Pressure (psi)		265	280	305	278	260
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 28

BALLOON COMPLIANCE
MEASUREMENTS BEFORE TESTING

	Double Wall Thickness Measurements		
	Proximal Side-Body	Center	Distal Side-Body
207	.00175	.00120	.00135
208	.00145	.00140	.00120
209	.00130	.00140	.00140
210	.00140	.00150	.00140
211	.00165	.00175	.00185
212	.00135	.00120	.00125
213	.00150	.00140	.00120
214	.00135	.00120	.00115
215	.00155	.00130	.00120
216	.00135	.00120	.00125
217	.00140	.00135	.00145
218	.00165	.00130	.00125
219	.00145	.00135	.00130
220	.00155	.00120	.00140
221	.00135	.00120	.00120
222	.00155	.00135	.00140
223	.00140	.00130	.00135
224	.00145	.00135	.00120
225	.00160	.00135	.00125
226	.00150	.00135	.00130
227	.00155	.00135	.00135
228	.00155	.00150	.00135
229	.00150	.00135	.00130
230	.00135	.00135	.00120
231	.00160	.00135	.00130
232	.00160	.00135	.00130
233	.00140	.00120	.00120
234	.00145	.00135	.00125
235	.00150	.00145	.00120
236	.00145	.00135	.00125

Examples 237-266

30 balloons were made according to the procedure described above for Examples 1-180.

The balloons were tested according to the procedure described above for Examples 1-180, except that balloons were tested at 1 atm increments from 4-16 atm and then burst.

Tables 29-35 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 29

BALLOON COMPLIANCE

PEBAX Grade: 6333
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	237	238	239	240	241
4	58.8	.114	.115	.114	.114	.114
5	73.5	.116	.118	.117	.117	.117
6	88.2	.118	.120	.120	.119	.119
7	102.5	.120	.122	.121	.121	.122
8	117.6	.122	.123	.123	.1230	.123
9	132.3	.123	.124	.124	.124	.125
10	147.0	.125	.126	.1260	.125	.126
11	161.7	.126	.127	.127	.127	.128
12	176.4	.128	.129	.128	.128	.129
13	191.1	.129	.130	.130	.130	.131
14	205.8	.130	.132	.132	.131	.132
15	220.5	.132	.134	.133	.133	.134
16	235.2	.133	.135	.135	Burst	.135
Burst Pressure (psi)		268	250	250	235	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 30

BALLOON COMPLIANCE

PEBAX Grade: 6333
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	242	243	244	245	246
4	58.8	.116	.115	.115	.114	.115
5	73.5	.119	.118	.117	.117	.117
6	88.2	.121	.120	.119	.119	.119
7	102.5	.122	.122	.121	.121	.121
8	117.6	.124	.124	.122	.1220	.122
9	132.3	.125	.125	.124	.124	.123
10	147.0	.127	.126	.125	.125	.125
11	161.7	.128	.128	.126	.126	.126
12	176.4	.129	.129	.128	.127	.128
13	191.1	.131	.131	.129	.129	.129
14	205.8	.133	.132	.131	.131	.130
15	220.5	.135	.134	.132	.132	.132
16	235.2	.136	.135	.134	.134	.133
Burst Pressure (psi)		250	250	250	250	260
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 31

BALLOON COMPLIANCE

PEBAX Grade:	6333
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	10 degrees
Rated Burst:	176 psi
Hold (Secs.)	15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	247	248	249	250	251
4	58.8	.115	.114	.116	.115	.115
5	73.5	.118	.118	.118	.118	.118
6	88.2	.120	.120	.120	.120	.120
7	102.5	.122	.122	.122	.121	.121
8	117.6	.123	.123	.123	.123	.123
9	132.3	.125	.125	.125	.124	.124
10	147.0	.127	.127	.126	.125	.125
11	161.7	.128	.128	.128	.127	.127
12	176.4	.129	.130	.129	.128	.128
13	191.1	.131	.131	.131	.130	.130
14	205.8	.133	.133	.132	.131	.131
15	220.5	.134	.135	.134	.133	.132
16	235.2	.135	.136	.136	.134	.134
Burst Pressure (psi)		250	250	250	250	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 32

BALLOON COMPLIANCE

PEBAX Grade: 6333
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	252	253	254	255	256
4	58.8	.114	.114	.115	.114	.115
5	73.5	.116	.117	.118	.117	.118
6	88.2	.119	.120	.120	.119	.120
7	102.5	.121	.122	.121	.121	.122
8	117.6	.122	.123	.122	.122	.123
9	132.3	.124	.124	.124	.123	.124
10	147.0	.125	.126	.125	.125	.126
11	161.7	.126	.127	.127	.126	.126
12	176.4	.128	.129	.129	.128	.127
13	191.1	.130	.130	.130	.129	.128
14	205.8	.131	.131	.131	.131	.131
15	220.5	.133	.133	.133	.133	.133
16	235.2	.135	.135	.135	.135	.135
Burst Pressure (psi)		250	250	250	250	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 33

BALLOON COMPLIANCE

PEBAX Grade:	6333
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	10 degrees
Rated Burst:	176 psi
Hold (Secs.)	15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	257	258	259	260	261
4	58.8	.115	.115	.114	.114	.115
5	73.5	.118	.117	.117	.117	.118
6	88.2	.120	.119	.119	.118	.120
7	102.5	.121	.120	.120	.120	.122
8	117.6	.123	.121	.121	.122	.123
9	132.3	.124	.122	.123	.123	.124
10	147.0	.125	.123	.124	.125	.125
11	161.7	.127	.125	.125	.126	.126
12	176.4	.128	.127	.127	.128	.128
13	191.1	.129	.129	.129	.129	.130
14	205.8	.131	.131	.130	.131	.132
15	220.5	.132	.132	.132	.133	.133
16	235.2	.134	.134	.134	.135	.134
Burst Pressure (psi)		250	235	250	250	260
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 34

BALLOON COMPLIANCE

PEBAX Grade: 6333
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	262	263	264	265	266
4	58.8	.115	.114	.114	.115	.115
5	73.5	.118	.117	.117	.117	.118
6	88.2	.119	.119	.118	.119.	.120
7	102.5	.121	.120	.120	.121	.121
8	117.6	.122	.121	.121	.122	.122
9	132.3	.123	.124	.122	.123	.124
10	147.0	.124	.125	.123	.124	.125
11	161.7	.126	.127	.125	.125	.126
12	176.4	.128	.128	.127	.127	.128
13	191.1	.129	.130	.129	.129	.129
14	205.8	.131	.131	.130	.130	.131
15	220.5	.133	.133	.132	.132	.133
16	235.2	.134	.135	.134	.135	.135
Burst Pressure (psi)		250	250	268	250	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 35

BALLOON COMPLIANCE
MEASUREMENTS BEFORE TESTING

	Double Wall Thickness Measurements		
	Proximal Side-Body	Center	Distal Side-Body
237	.00155	.00130	.00120
238	.00135	.00120	.00120
239	.00125	.00120	.00110
240	.00125	.00120	.00120
241	.00130	.00120	.00120
242	.00135	.00120	.00110
243	.00130	.00115	.00120
244	.00130	.00120	.00110
245	.00135	.00125	.00110
246	.00135	.00120	.00120
247	.00135	.00120	.00115
248	.00125	.00120	.00115
249	.00120	.00120	.00110
250	.00130	.00125	.00110
251	.00130	.00120	.00115
252	.00135	.00120	.00105
253	.00130	.00120	.00110
254	.00120	.00110	.00110
255	.00120	.00115	.00105
256	.00125	.00120	.00110
257	.00125	.00120	.00110
258	.00135	.00120	.00110
259	.00135	.00120	.00115
260	.00120	.00110	.00110
261	.00130	.00125	.00120
262	.00130	.00120	.00110
263	.00125	.00120	.00115
264	.00130	.00115	.00115
265	.00135	.00120	.00110
266	.00120	.00110	.00105

Examples 267-276

10 balloons were made according to the procedure described above for Examples 1-180, except that parisons had inside diameters of about .025 inches and wall thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

Tables 36-38 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 36

BALLOON COMPLIANCE

PEBAX Grade:	7033
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	10 degrees
Rated Burst:	176 psi
Hold (Secs.)	15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	267	268	269	270	271
4	58.8	.112	.113	.113	.113	.113
5	73.5	.116	.116	.116	.116	.116
6	88.2	.118	.118	.118	.118	.118
7	102.5	.120	.119	.120	.119	.119
8	117.6	.121	.120	.121	.120	.120
9	132.3	.122	.121	.122	.121	.121
10	147.0	.123	.122	.124	.122	.123
11	161.7	.124	.123	.125	.124	.124
12	176.4	.125	.125	.126	.124	.125
13	191.1	.126	.127	.127	.125	.126
14	205.8	.127	.1275	.128	.127	.127
15	220.5	.128	.128	.129	.1275	.128
16	235.2	.129	.129	.130	.1285	.129
Burst Pressure (psi)		263	264	250	264	250
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 37

BALLOON COMPLIANCE

PEBAX Grade: 7033
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure		DIAMETER (inches) Balloon Number				
atm	psi	272	273	274	275	276
4	58.8	.112	.114	.114	.114	.113
5	73.5	.115	.117	.116	.117	.116
6	88.2	.117	.118	.117	.118	.118
7	102.5	.1185	.120	.119	.120	.120
8	117.6	.121	.121	.120	.121	.122
9	132.3	.122	.122	.121	.122	.122
10	147.0	.123	.123	.123	.123	.123
11	161.7	.124	.124	.124	.124	.124
12	176.4	.126	.126	.125	.125	.125
13	191.1	.128	.1265	.127	.126	.126
14	205.8	.128	.1280	.128	.127	.127
15	220.5	.129	.129	.1295	.128	.128
16	235.2	.130	.130	.131	.129	.129
Burst Pressure (psi)		250	264	264	250	264
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 38

BALLOON COMPLIANCE
MEASUREMENTS BEFORE TESTING

	Double Wall Thickness Measurements		
	Proximal Side-Body	Center	Distal Side-Body
267	.00110	.00110	.00105
268	.00105	.00105	.00105
269	.00105	.00100	.00100
270	.00110	.00110	.00110
271	.00115	.00110	.00100
272	.00115	.00100	.00100
273	.00115	.00110	.00100
274	.00115	.00100	.00105
275 -	.00110	.00110	.00100
276	.00110	.00100	.00100

Examples 277-306

30 balloons were made according to the procedure described above for Examples 1-180, except that cone angles were 267 and the parison inside diameter was .025 inches with a wall thickness of .0065.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

Tables 39-41 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 39

BALLOON COMPLIANCE

PEBAX Grade:	7033
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	26°
Rated Burst:	176
Hold (Secs.)	15

Pressure	DIAMETER (cm) Balloon Numbers									
atm	277	278	279	280	281	282	283	284	285	286
4	2.9972	3.0226	2.9718	2.9210	2.9210	2.9210	2.8448	2.8194	2.8956	2.9210
5	3.0988	3.1242	3.0988	3.0226	2.9972	2.9972	2.9972	2.9972	3.0226	3.0480
6	3.1496	3.1750	3.1496	3.1242	30.7340	3.1496	30.9880	3.0988	3.1750	3.1496
7	3.2004	3.2258	3.2004	3.1750	3.1750	3.2258	3.2004	3.2004	3.2258	3.2004
8	3.2766	3.2512	3.2258	3.2258	3.2258	3.2766	3.2512	3.2512	3.2766	3.3020
9	3.3020	3.3020	3.2766	3.2766	3.2766	3.3528	3.3020	3.3020	3.3274	3.3528
10	3.3528	3.3528	3.3274	3.3030	3.3274	3.4036	3.3528	3.3528	3.4036	3.4036
11	3.3782	3.4036	3.3782	3.3528	3.3782	3.4544	3.4036	3.4036	3.4544	3.4544
12	3.4544	3.4544	3.4290	3.4036	3.4036	3.5052	3.4544	3.4544	3.5306	3.5306
13	3.5052	3.4798	3.5052	3.4290	3.4544	3.5814	3.5052	3.5052	3.5814	3.6068
14	3.5560	3.5560	3.5814	3.5052	3.5052	3.6576	3.5560	3.5560	3.6576	3.6576
15	3.5814	3.6068	3.6068	3.5306	3.5306	3.7338	3.6068	3.6322	3.8100	3.7592
16	3.6576	3.6830	3.6322	3.6068	3.6068	3.8608	3.6576	3.6576	3.8100	3.8100
Burst psi	290	265	265	295	260	265	265	260	250	265
atm	19.70	18.02	18.02	20.06	17.68	18.02	18.02	17.68	17.00	18.02

Table 40

BALLOON COMPLIANCE

PEBAX Grade: 7033
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 26°
Rated Burst: 176
Hold (Secs.) 15

Pressure	DIAMETER (cm) Balloon Numbers									
atm	287	288	289	290	291	292	293	294	295	296
4	2.8956	2.8956	2.9210	2.8702	2.8956	2.9718	2.8956	2.9464	2.9210	2.8702
5	2.9972	2.9972	3.0480	2.9972	3.0226	3.0988	3.0226	3.0734	3.0480	2.9718
6	3.1242	3.0988	3.1496	3.0988	3.1242	3.1750	3.1242	3.1750	3.1242	3.0734
7	3.2004	3.2004	3.2258	3.1496	3.1750	3.2512	3.1750	3.2258	3.2004	3.1750
8	3.2512	3.2258	3.3020	3.2258	3.2512	3.3020	3.2258	3.2766	3.2512	3.2258
9	3.3274	3.3020	3.3528	3.2766	3.3020	3.3528	3.2766	3.3274	3.3274	3.2766
10	3.3782	3.3528	3.4036	3.3274	3.3528	3.4036	3.3274	3.3782	3.3782	3.3274
11	3.4290	3.4036	3.4798	3.3782	3.4036	3.4544	3.3782	3.4290	3.4290	3.3782
12	3.4798	3.4544	3.5560	3.4290	3.4544	3.5052	3.4290	3.5052	3.4798	3.4290
13	3.5560	3.5306	3.6068	3.4798	3.5052	3.5306	3.4544	3.5560	3.5560	3.4798
14	3.6068	3.5560	3.6576	3.5306	3.5560	3.5306	3.5052	3.6068	3.6068	3.5052
15	3.6576	3.6068	3.7338	3.5814	3.6322	3.5306	3.5306	3.6830	3.6830	3.5814
16	3.7592	3.6576	3.8354	3.6576	3.7084	3.5560	3.5560	3.7592	3.6830	3.6322
Burst psi	265	265	265	265	265	265	265	260	250	265
atm	18.02	18.02	18.02	18.02	18.02	18.02	18.02	17.68	17.00	18.02

Table 41

BALLOON COMPLIANCE

PEBAX Grade:	7033
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	26°
Rated Burst:	176
Hold (Secs.)	15

Pressure	DIAMETER (cm) Balloon Numbers									
atm	297	298	299	300	301	302	303	304	305	306
4	2.8702	2.8956	2.8194	2.8194	2.8702	2.7940	2.8448	2.8702	2.8956	2.8448
5	2.9972	2.9972	2.9972	2.9210	2.9972	2.9972	2.9972	2.9718	2.9972	2.9972
6	3.1242	3.1242	3.0988	3.0480	3.0988	3.1242	3.0988	3.0734	3.0988	3.0988
7	3.1750	3.1750	3.2004	3.1496	3.1750	3.2004	3.1750	3.1496	3.1750	3.2004
8	3.2512	3.2512	3.2512	3.2004	3.2258	3.2512	3.2512	3.2004	3.2258	3.2766
9	3.3274	3.3020	3.2766	3.2512	3.3020	3.3274	3.3020	3.2512	3.2766	3.3274
10	3.3782	3.3528	3.3274	3.3274	3.3528	3.4036	3.3274	3.3020	3.3274	3.4036
11	3.4544	3.4036	3.3782	3.3782	3.4036	3.4544	3.3782	3.3782	3.3782	3.4544
12	3.5052	3.4798	3.4555	3.4036	3.4544	3.5052	3.4544	3.4290	3.4290	3.5052
13	3.5560	3.5052	3.5306	3.4544	3.5052	3.6068	3.5052	3.4544	3.4798	3.5814
14	3.6322	3.5306	3.5814	3.5052	3.5560	3.6576	3.5560	3.5052	3.5306	3.6322
15	3.6830	3.5814	3.6322	3.5560	3.6322	3.7592	3.6068	3.5560	3.5814	3.7084
16	3.7846	3.6322	3.7084	3.6322	3.6830	3.8100	3.6830	3.6322	3.6322	3.7846
Burst psi	265	260	265	265	265	265	265	265	265	265
atm	18.02	17.68	18.02	18.02	18.02	18.02	18.02	18.02	18.02	18.02

Examples 307-366

60 balloons were made according to the following procedure: Tubing was placed into a mold and preheated for 15-30 seconds to a preselected balloon blowing temperature. The tubing was stretched and inflated to make a balloon. The balloon was allowed to remain at the balloon blowing temperature for 15-30 seconds, and then elevated to at least the crystallization temperature for 10-20 seconds. The balloon was then cooled to room temperature and removed from the mold.

The balloons were tested according to the procedure described above for Examples 1-180.

Tables 42-47 below list certain parameters (PEBAX grade, dimensions, crystallization temperature, mold temperature, left and right stretch dimensions, nitrogen pressure, and air flow). The tables also show results of the testing of the expander members.

Table 42

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	200° F	MOLD:	190° F
STRETCH:	LEFT:	2.60 INCHES	RIGHT:	2.60 INCHES
PSI:	350			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
307	0.00120	0.00120	0.00130	.020x.035	0.119	0.128	0.135	238
308	0.00120	0.00130	0.00120	.020x.035	0.118	0.127	0.137	241
309	0.00135	0.00135	0.00145	.020x.035	0.118	0.128	0.136	245
310	0.00130	0.00140	0.00120	.020x.035	0.117	0.127	0.137	238
311	0.00125	0.00135	0.00145	.020x.035	0.117	0.127	0.134	240
312	0.00135	0.00125	0.00125	.020x.035				249
313	0.00125	0.00125	0.00125	.020x.035				239
314	0.00135	0.00130	0.00130	.020x.035				230
315	0.00130	0.00130	0.00130	.020x.035				240
316	0.00130	0.00130	0.00135	.020x.035				240
Average	0.001285	0.0013	0.001305	.020x.035	0.1178	0.1274	0.1358	240
Standard	5.79751E-05	5.7735E-05	8.95979E-05		0.000837	0.000548	0.001304	4.898979

Calculated K-stat (psi): 214.5106

Calculated Hoop Stress (psi): 23794.55

Table 43

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	260° F	MOLD:	190° F
STRETCH:	LEFT:	2.75 INCHES	RIGHT:	2.75 INCHES
PSI:	350			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
317	0.00130	0.00135	0.00130	.020x.035	0.116	0.127	0.135	240
318	0.00135	0.00140	0.00140	.020x.035	0.114	0.127	0.135	248
319	0.00135	0.00145	0.00135	.020x.035	0.116	0.127	0.134	240
320	0.00135	0.00135	0.00145	.020x.035	0.115	0.127	0.134	251
321	0.00130	0.00145	0.00130	.020x.035	0.115	0.127	0.135	240
322	0.00145	0.00135	0.00135	.020x.035				240
323	0.00140	0.00140	0.00140	.020x.035				248
324	0.00135	0.00135	0.00140	.020x.035				240
325	0.00135	0.00135	0.00135	.020x.035				240
326	0.00135	0.00135	0.00135	.020x.035				240
Average	0.001355	0.00138	0.00137	.020x.035	0.1152	0.127	0.1346	242.7
Standard	4.38E-05	4.216E-05	4.74342E-05		0.000837	1.86E-09	0.000548	4.423423

Calculated K-stat (psi): 219.6849

Calculated Hoop Stress (psi): 22747.53

Table 44

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 30 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	200° F	MOLD:	190° F
STRETCH:	LEFT:	2.75 INCHES	RIGHT:	2.75 INCHES
PSI:	380			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
327	0.00130	0.001350	0.00130	.020x.035	0.115	0.125	0.129	270
328	0.00125	0.001300	0.00130	.020x.035	0.116	0.125	0.129	270
329	0.00130	0.001350	0.00130	.020x.035	0.116	0.125	0.132	270
330	0.00130	0.001300	0.00125	.020x.035	0.115	0.127	0.132	263
331	0.00125	0.001300	0.00130	.020x.035	0.116	0.126	0.132	270
332	0.00135	0.001350	0.00130	.020x.035				280
333	0.00135	0.001300	0.00130	.020x.035				280
334	0.00130	0.001300	0.00130	.020x.035				270
335	0.00125	0.001250	0.00120	.020x.035				283
336	0.00130	0.001200	0.00130	.020x.035				240
Average	0.001295	0.0013	1.285E-03	.020x.035	0.1156	0.1256	0.1308	269.6
Standard	3.69E-05	4.714E-05	3.37474E-05		0.000548	0.000894	0.001643	12.09408

Calculated K-stat (psi): 206.6745

Calculated Hoop Stress (psi): 26148.08

Table 45

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 30 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	260° F	MOLD:	210° F
STRETCH:	LEFT:	2.25 INCHES	RIGHT:	2.25 INCHES
PSI:	320			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
337	0.00100	0.00100	0.00100	.020x.035	0.121	0.13	0.138	238
338	0.00115	0.00120	0.00100	.020x.035	0.121	0.129	0.136	230
339	0.00100	0.00105	0.00115	.020x.035	0.121	0.13	0.138	220
340	0.00110	0.00115	0.00100	.020x.035	0.121	0.129	0.136	219
341	0.00105	0.00110	0.00100	.020x.035	0.121	0.129	0.137	238
342	0.00105	0.00100	0.00100	.020x.035				239
343	0.00120	0.00120	0.00105	.020x.035				238
344	0.00100	0.00110	0.00105	.020x.035				238
345	0.00100	0.00105	0.00105	.020x.035				220
346	0.00105	0.00110	0.00100	.020x.035				239
Average	0.00106	0.001095	0.00103	.020x.035	0.121	0.1294	0.137	231.9
Standard	6.99E-05	7.246E-05	4.83046E-05		0	0.000548	0.001	8.83742

Calculated K-stat (psi): 185.9189

Calculated Hoop Stress (psi): 28309.3

Table 46

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	400° F	MOLD:	190° F
STRETCH:	LEFT:	2 INCHES	RIGHT:	2 INCHES
PSI:	400			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
347	0.00140	0.00140	0.00140	.020x.035	0.113	0.119	0.124	305
348	.0.00145	0.00150	0.00145	.020x.035	0.111	0.119	0.124	330
349	0.00145	0.00150	0.00150	.020x.035	0.113	0.122	0.124	315
350	0.00140	0.00140	0.00140	.020x.035	0.115	0.122	0.125	313
351	0.00150	0.00145	0.00140	.020x.035	0.113	0.120	0.124	343
352	0.00145	0.00145	0.00135	.020x.035				343
353	0.00150	0.00150	0.00140	.020x.035				329
354	0.00140	0.00150	0.00140	.020x.035				303
355	0.00140	0.00140	0.00140	.020x.035				313
356	0.00140	0.00150	0.00140	.020x.035				330
Average	0.001433	0.00146	0.00141	.020x.035	0.113	0.1204	0.1242	322.4
Standard	4.33E-05	4.595E-05	3.94405E-05		0.001414	0.001517	0.000447	14.59985

Calculated K-stat (psi): 246.437

Calculated Hoop Stress (psi): 27081.6

Table 47

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:	CRYSTALIZATION:	260° F	MOLD:	210° F
STRETCH:	LEFT:	2.25 INCHES	RIGHT:	2.25 INCHES
PSI:	330			
AIRFLOW:	200			

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
357	0.00110	0.00100	0.00125	.020x.035	0.118	0.125	0.128	240
358	0.00100	0.00105	0.00115	.020x.035	0.119	0.125	0.13	260
359	0.00100	0.00105	0.00120	.020x.035	0.118	0.123	0.128	242
360	0.00110	0.00120	0.00100	.020x.035	0.119	0.126	0.131	245
361	0.00110	0.00120	0.00120	.020x.035	0.119	0.125	0.13	260
362	0.00100	0.00100	0.00120	.020x.035				260
363	0.00120	0.00120	0.00130	.020x.035				242
364	0.00115	0.00105	0.00120	.020x.035				262
365	0.00100	0.00105	0.00120	.020x.035				260
366	0.00110	0.00100	0.00115	.020x.035				231
Average	0.001075	0.00108	0.001185	.020x.035	0.1186	0.1248	0.1294	250.2
Standard	7.17E-05	8.5635E-05	7.83511E-05		0.000548	0.001095	0.001342	11.34117

Calculated K-stat (psi): 191.192
Calculated Hoop Stress (psi): 29046.47

Figures 4-15 were prepared by collecting data according to material type, and reducing the data to a series of quadratic equations that include stretch, crystallization temperature, and balloon blowing temperature as dependant variables. The equations were then plotted using a statistical design of experiments program called ECHIP®. Response variables of interest were then plotted.

With regard to Figures 4-15, the balloons were expanded to two times their original length in the axial direction.

The foregoing specification and figures are presented for the purpose of illustrating, and not limiting, the present invention.

CLAIMS

1. A balloon for an angioplasty device having a single polymeric layer comprising (a) from about 20 to about 100 weight percent polyesteretheramide copolymer, and (b) from about 0 to about 80 weight percent polyamide; wherein the polymeric layer contains substantially no polyetheramide having substantially no ester linkages.

2. The balloon of claim 1 wherein the polyesteretheramide copolymer comprises a block copolymer.

3. The balloon of claim 1 wherein the polyesteretheramide copolymer comprises a random copolymer.

4. The balloon of claim 1 wherein the polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.

5. The balloon of claim 4 wherein the polyesteretheramide copolymer has a hardness of from about 55 Shore D to about 75 Shore D.

6. The balloon of claim 5 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.

7. The balloon of claim 6 wherein the polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.

8. The balloon of claim 1 wherein the single polymeric layer comprises at least about 2 weight percent polyamide.

9. The balloon of claim 8 wherein the polyamide is selected from the group consisting of nylon 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and combinations thereof.

10. The balloon of claim 9 comprising from about 20 to about 80 weight percent nylon 12 and about 20 to about 80 weight percent polyesteretheramide copolymer.

11. The balloon of claim 10 comprising about 60 weight percent nylon 12 and about 40 weight percent polyesteretheramide copolymer.

12. The balloon of claim 9 comprising from about 25 to about 80 weight percent nylon 4/6 and about 20 to about 75 weight percent polyesteretheramide copolymer.

13. The balloon of claim 12 comprising about 65 weight percent nylon 4/6 and about 35 weight percent polyesteretheramide copolymer.

14. The balloon of claim 1 wherein the single polymeric layer further comprises at least about 2 weight percent of a polymer selected from polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

15. The balloon of claim 1 wherein the polymeric layer comprises at least about 40 weight percent polyesteretheramide copolymer.

16. The balloon of claim 15 wherein the polymeric layer comprises at least about 80 weight percent polyesteretheramide copolymer.

17. A balloon for an angioplasty device having a single polymeric layer consisting essentially of a polyesteretheramide copolymer.

18. The balloon of claim 17 wherein the polyesteretheramide copolymer comprises a block copolymer.

19. The balloon of claim 17 wherein the polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.

20. The balloon of claim 19 wherein the polyesteretheramide copolymer has a hardness of from about 55 Shore D to about 75 Shore D.

21. The balloon of claim 20 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.

22. The balloon of claim 21 wherein the polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.

23. The balloon of claim 17 consisting of a polyesteretheramide copolymer.

24. A balloon for an angioplasty device having a single polymeric layer comprising (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and (c) from 0 to 9 weight percent of a polymer other than polyesteretheramide and polyamide.

25. The balloon of claim 24 comprising at least about 95 weight percent polyesteretheramide copolymer.

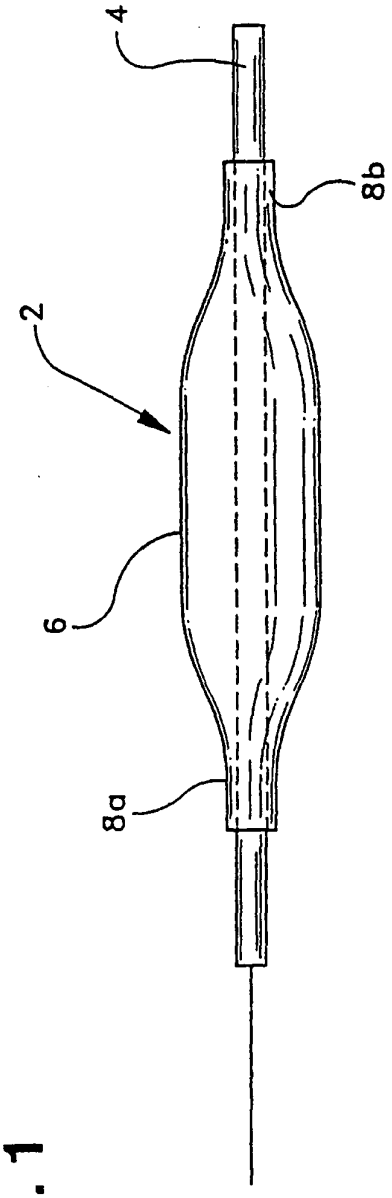


FIG. 1

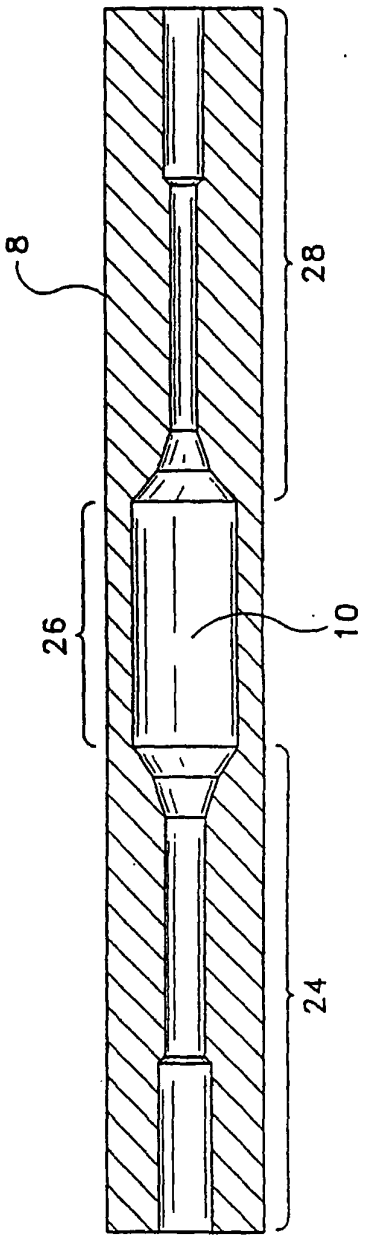


FIG. 2

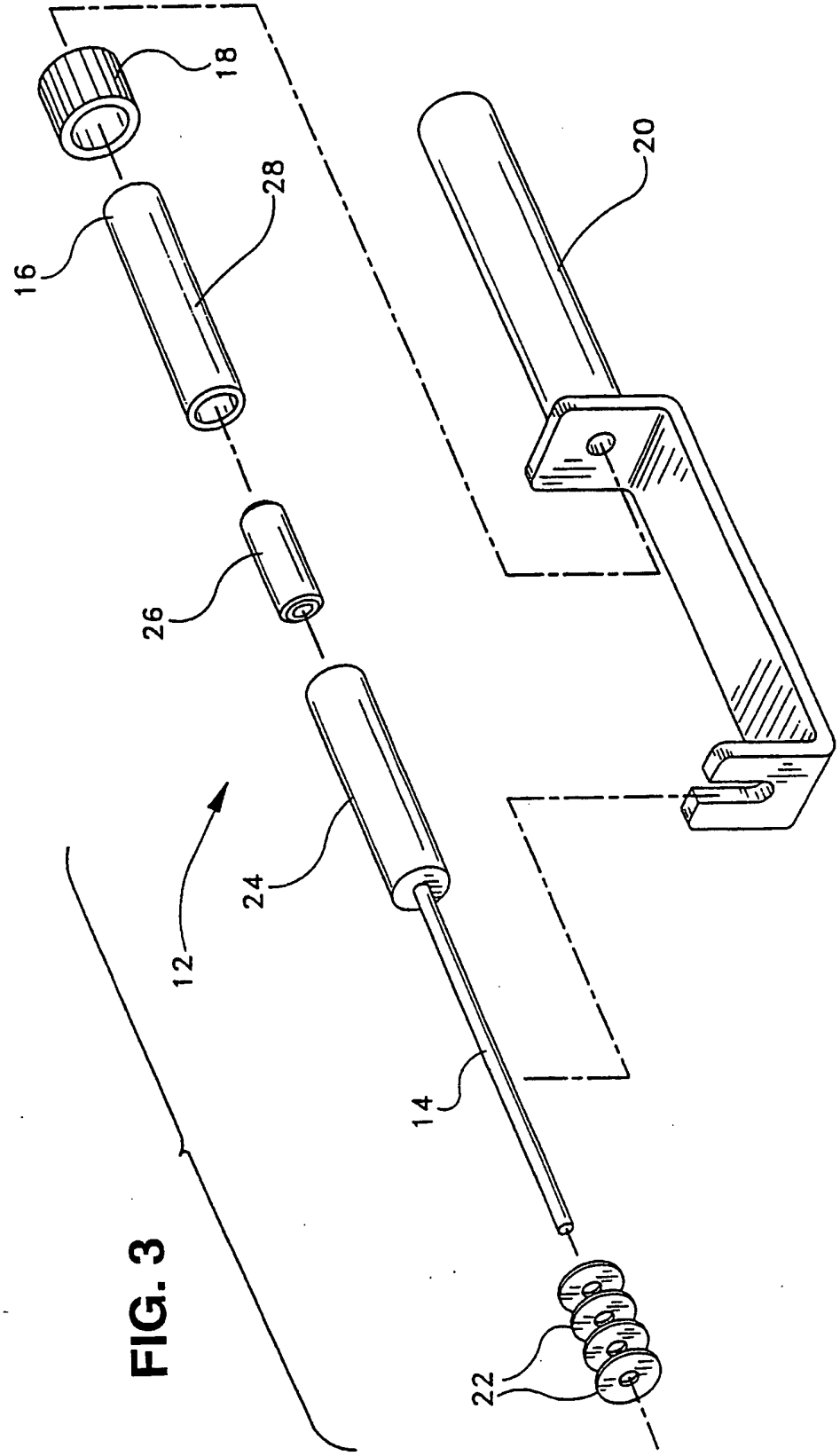


FIG. 3

FIG. 4

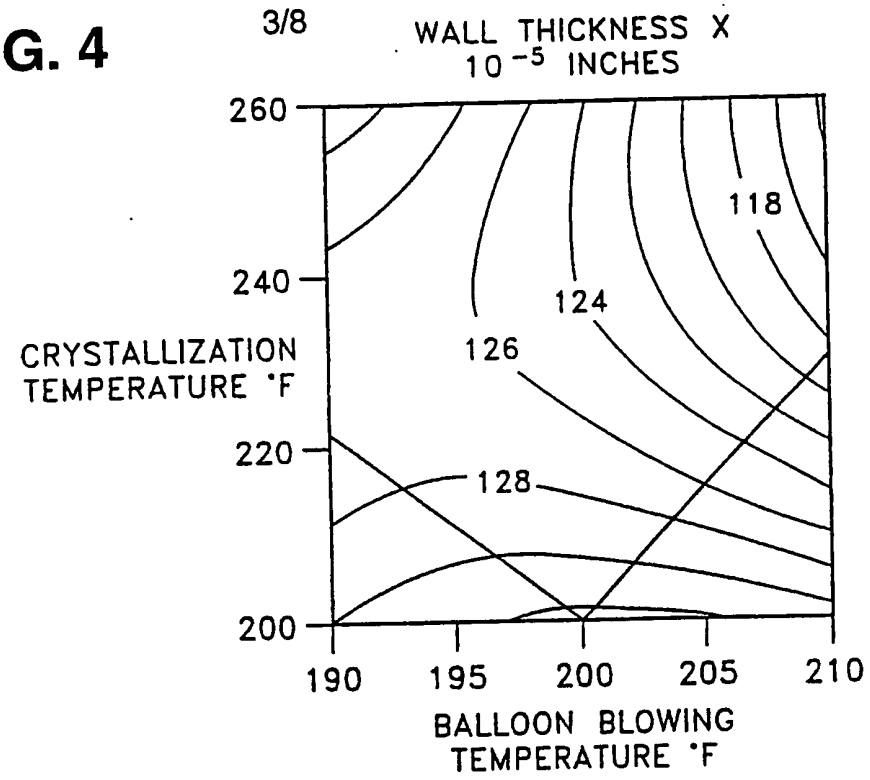

WALL THICKNESS X
10 -5 INCHES
260
240
220
200
CRYSTALLIZATION
TEMPERATURE °F
118
124
126
128
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 5

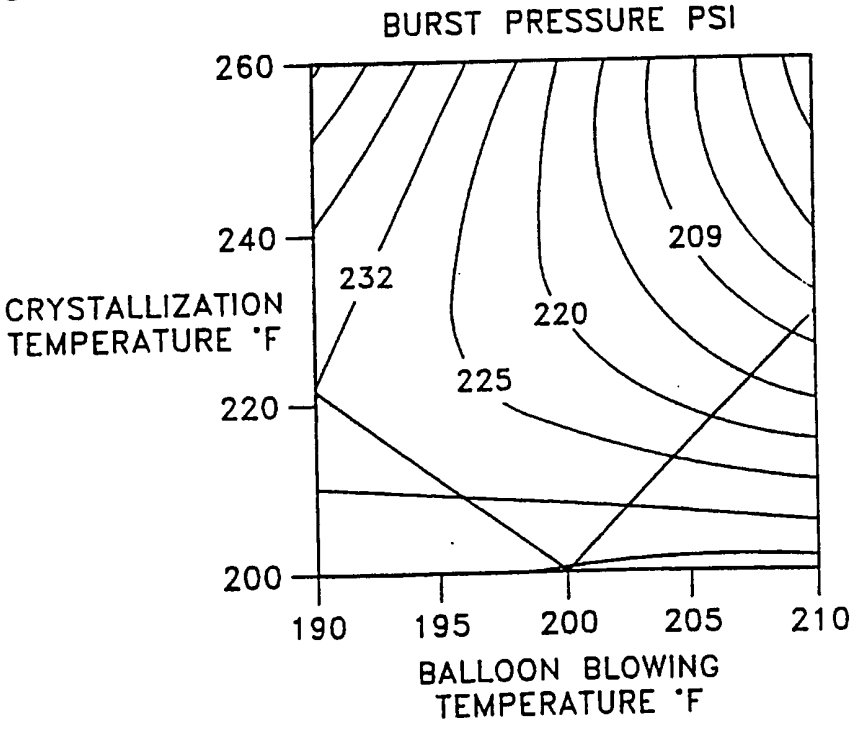
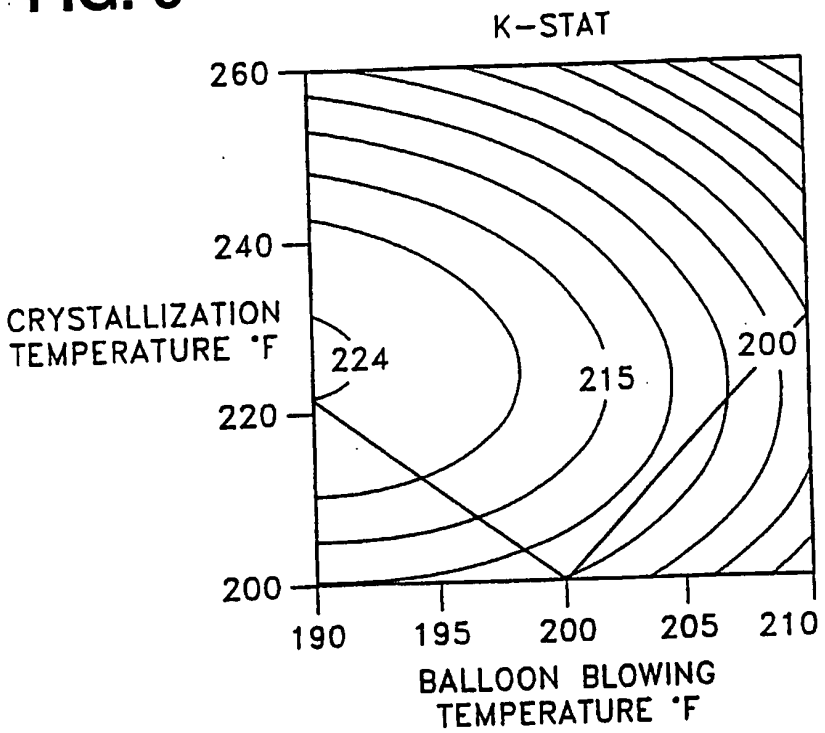

BURST PRESSURE PSI
260
240
220
200
CRYSTALLIZATION
TEMPERATURE °F
232
225
220
209
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 6


K-STAT
260
240
220
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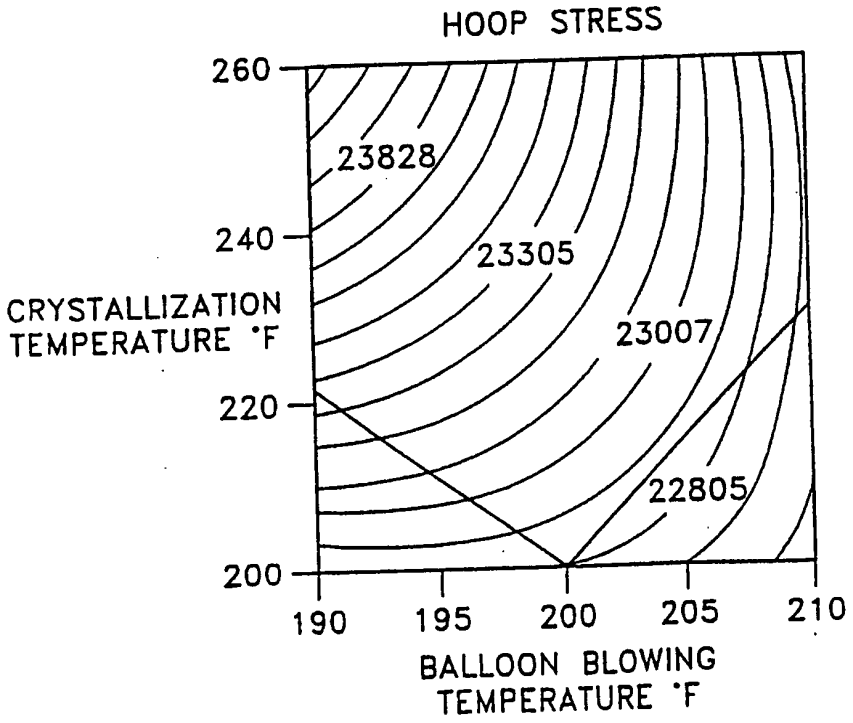
CRYSTALLIZATION TEMPERATURE °F
224
215
200
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

FIG. 7


HOOP STRESS
260
240
220
200
CRYSTALLIZATION TEMPERATURE °F
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23305
23007
22805
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

FIG. 8

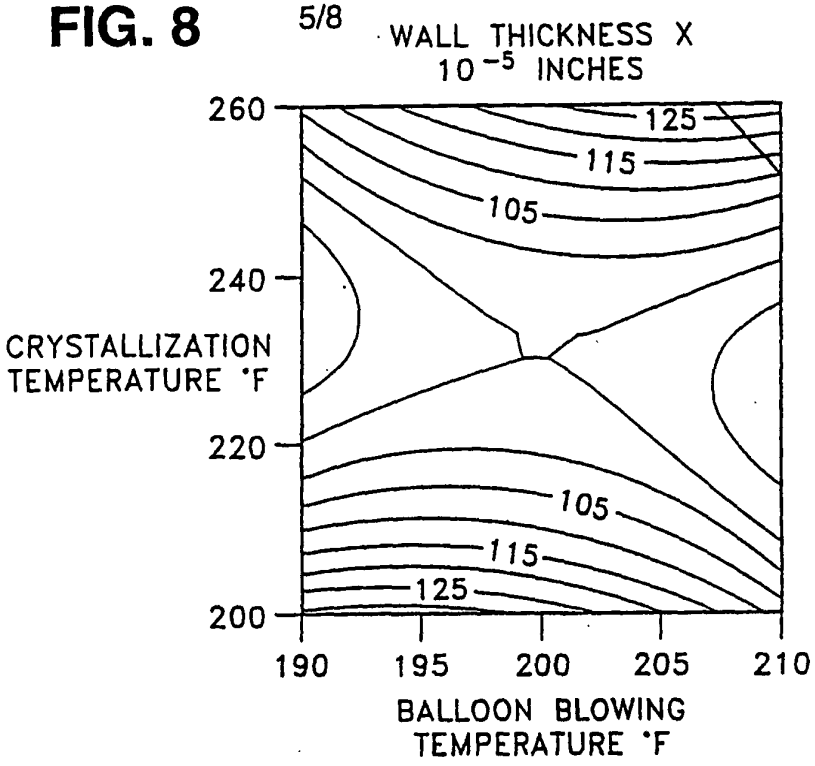
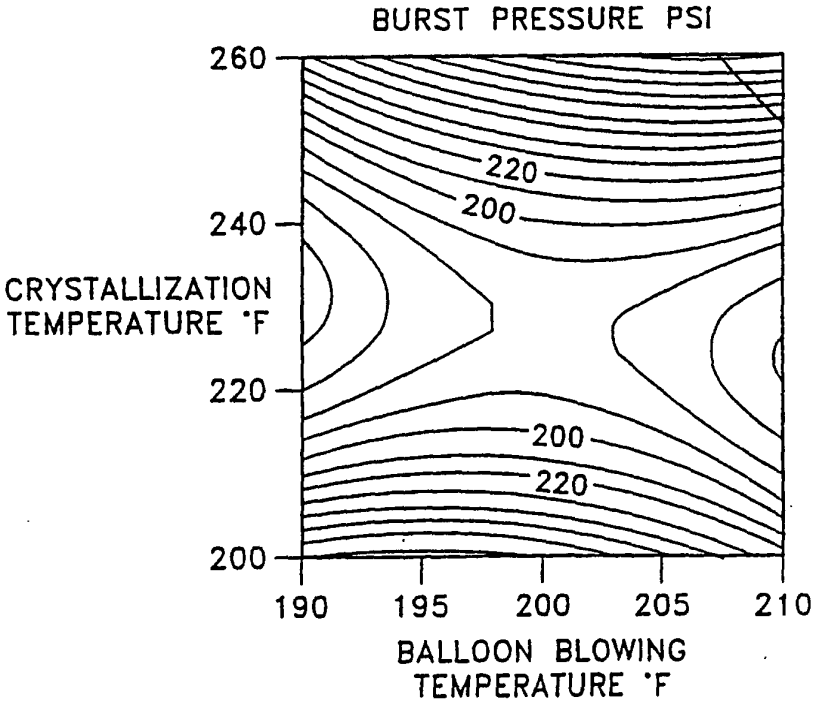

WALL THICKNESS X
10 -5 INCHES
260
240
220
200
125
115
105
105
115
125
CRYSTALLIZATION
TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 9


BURST PRESSURE PSI
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240
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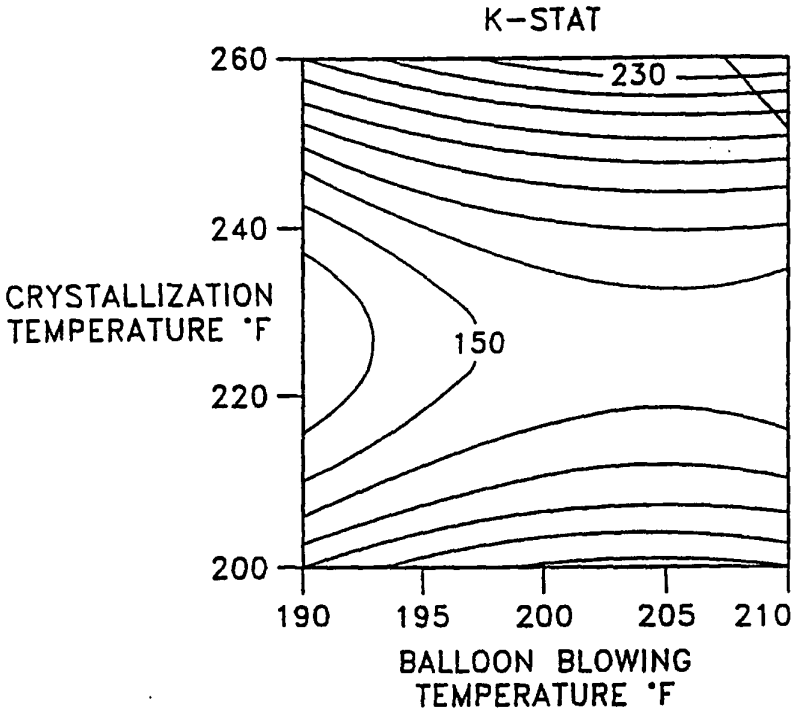
200
220
200
200
220
CRYSTALLIZATION
TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 10


K-STAT
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230
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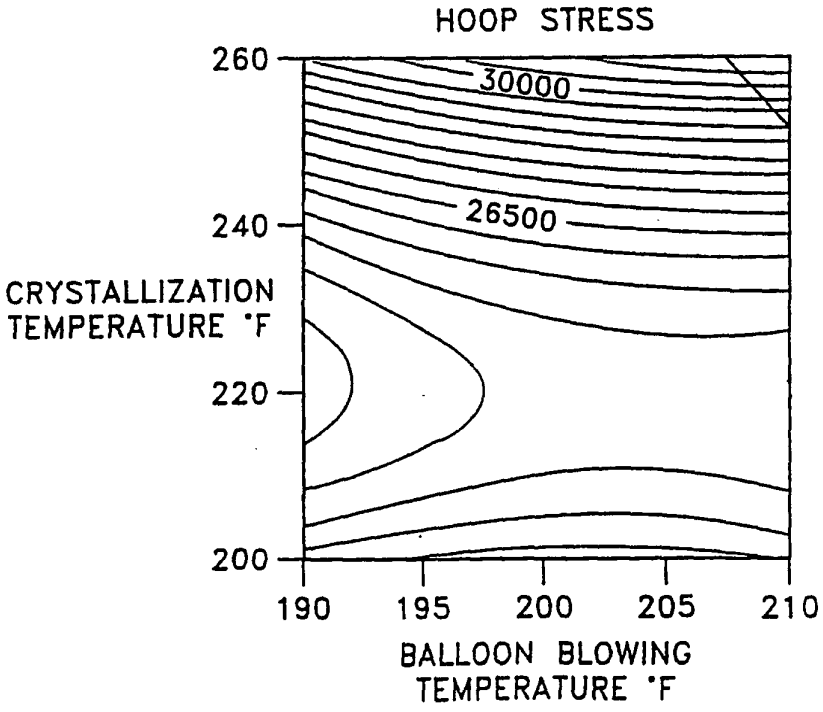
CRYSTALLIZATION TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

FIG. 11


HOOP STRESS
260
240
220
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30000
26500
CRYSTALLIZATION TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

FIG. 12

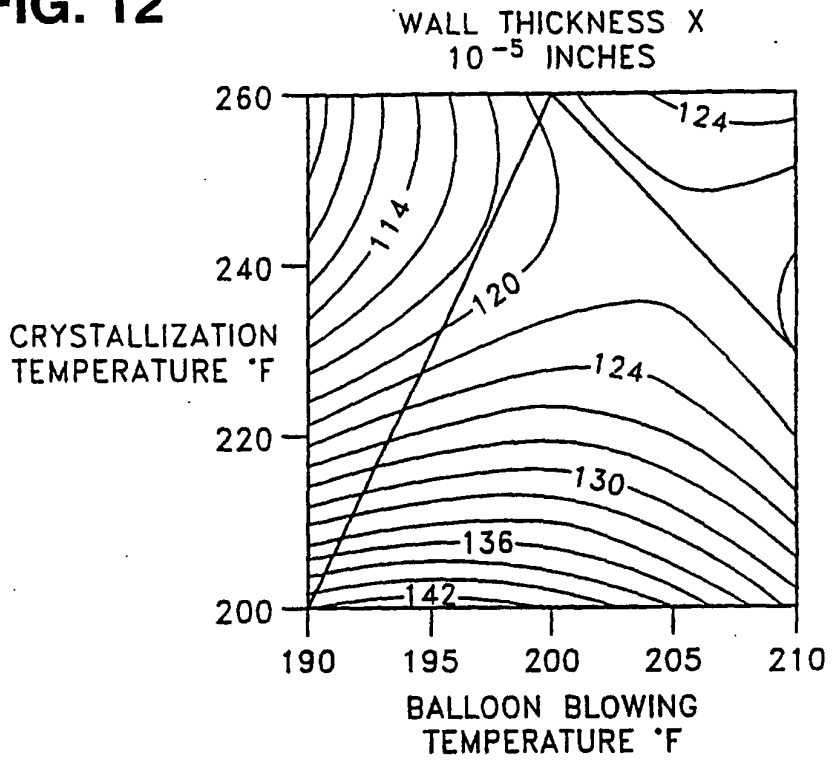

WALL THICKNESS X
10 -5 INCHES
260
240
220
200
CRYSTALLIZATION
TEMPERATURE °F
114
120
124
124
130
136
142
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 13

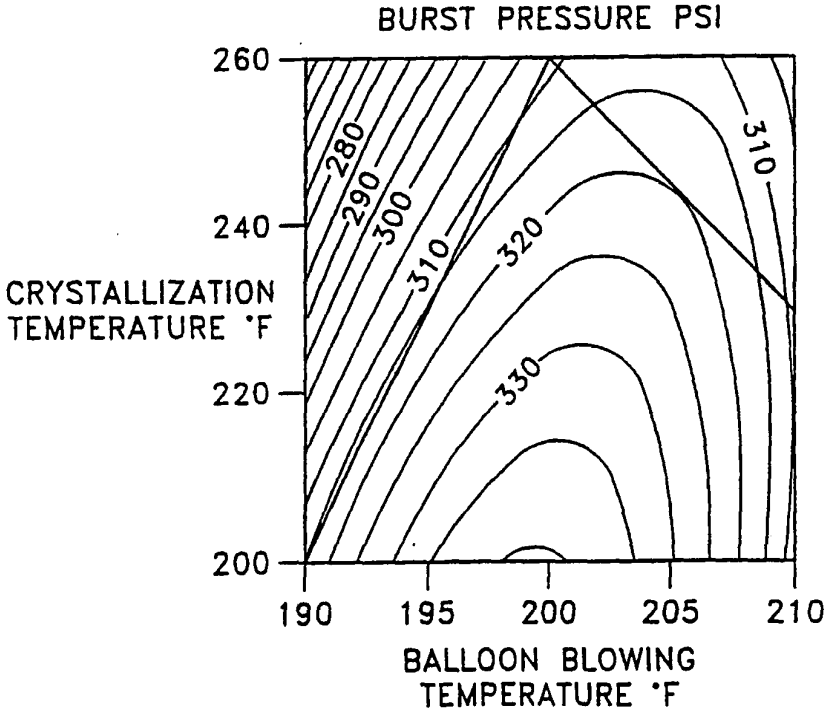
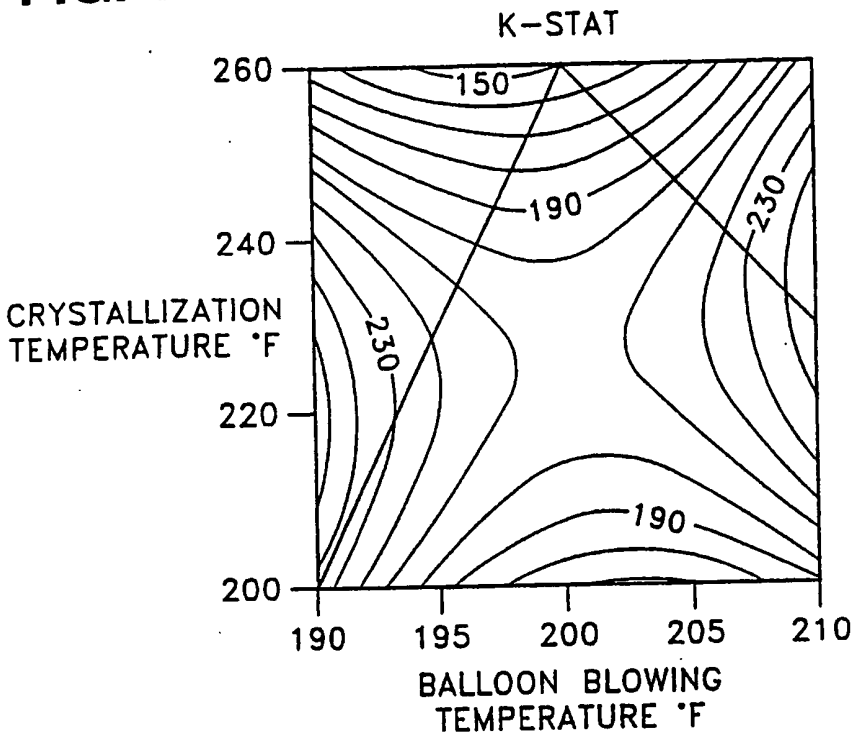

BURST PRESSURE PSI
260
240
220
200
CRYSTALLIZATION
TEMPERATURE °F
280
290
300
310
320
330
310
190
195
200
205
210
BALLOON BLOWING
TEMPERATURE °F

FIG. 14


K-STAT
260
240
220
200
150
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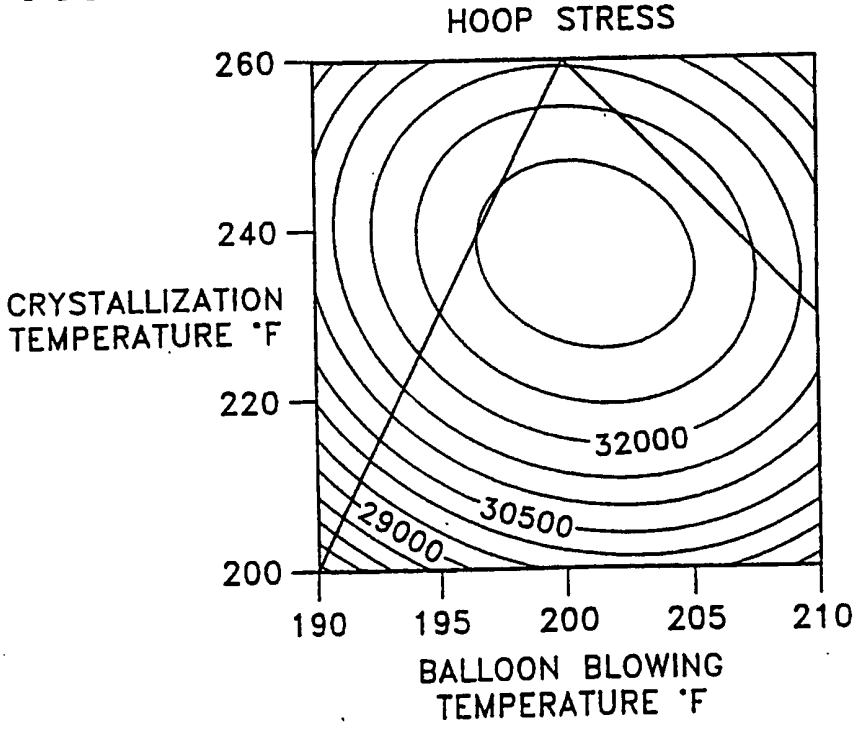
230
190
CRYSTALLIZATION TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

FIG. 15


HOOP STRESS
260
240
220
200
32000
30500
29000
CRYSTALLIZATION TEMPERATURE °F
190
195
200
205
210
BALLOON BLOWING TEMPERATURE °F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 96/00291

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO,A,95 23619 (SCIMED LIFE SYSTEMS) 8 September 1995 see page 5, line 2 - page 6, line 24 see claims 1-4; examples 1-9,11,13	1,2,4-7, 15-25
P,X	EP,A,0 697 219 (ADVANCED CARDIOVASCULAR SYSTEMS) 21 February 1996 see page 5, line 15 - line 16; claim 3	1
X	EP,A,0 537 069 (TERUMO) 14 April 1993 cited in the application see claims 1,6,7	1,8
A	FR,A,2 651 681 (MEDICORP RESEARCH) 15 March 1991 see claims 1,3	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 1996	05. 11. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Peltre, C

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 96/00291

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,90 01345 (MALLINCKRODT) 22 February 1990 see page 8, line 3 - line 31	1
A	EP,A,0 117 093 (MALLINCKRODT) 29 August 1984 see claims 1-9	1
A	WO,A,84 01513 (HARDCASTLE D.) 26 April 1984 see claims 3,4	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 96/00291

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		DE-T- 68912943	11-05-94
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